MAY 25 2004

K032977

510(K) Summary

I. Submitter / 510(K) Sponsor

JMS North America Corporation.
22320 Foothill Blvd., Suite 350
Hayward, CA 94541
U.S.A.

Contact: Swee Cheau, Chong
Manager of Regulatory Affairs & Quality Assurance
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Date Prepared: Sep 16, 2003

II. Device Name

Classification Name : Cardiopulmonary bypass vascular catheter, cannula, or tubing
Classification Number: 21 CFR 870.4210
Device Classification : Class II Device
Trade Name : JMS Bypass Tube

III. Substantial Equivalence Predicate Device

Name : T-AnastaFLO
510(K) Number : K990396
Manufacturer : Baxter Research Medical, Inc.
SE Decision Date : Oct 1st, 1999

IV. Device Description

The JMS Bypass Tube is a sterile, single use, consists of a tube shaft made by nylon with bulging bulbs at the distal ends. A guide-wire is inserted within the tube shaft to guide the easy insertion of tube shunt into target vessel. A tab on a thread is attached near to the mid-point of the flexible shaft. Each JMS Bypass Tube is individually packaged sterile and non-pyrogenic in a sealed, peel type pouch.

V. Intended Use

JMS Bypass Tube is indicated to be used to as temporary bypass shunt to internally shunt blood vessels during anastomosis constructions, hence preventing ischemia. The bypass shunt is to be removed prior to the final sutures being performed. The device is for single use only.

VI. Safety and Effectiveness

Non-clinical performance testing was conducted and had demonstrated that JMS Bypass Tube is safe and effective for use as intended and the device is substantially equivalent to existing predicate devices. All materials used in JMS Bypass Tube conforms to FDA recognized consensus standard ISO 10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 25 2004

JMS North America Corporation
c/o Ms. Chong Swee Cheau
Manager of Regulatory Affairs & Quality Assurance
22320 Foothill Blvd., Suite 350
Hayward, CA 94541

Re: K032977
JMS Bypass Tube
Regulation Number: 21 CFR 870.4210
Regulation Name: Vascular Catheter, Cannula, or Tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: May 13, 2004
Received: May 14, 2004

Dear Ms. Chong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R Vochmel

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K032977

Device Name: JMS Bypass Tube / Class II

Indications For Use:

JMS Bypass Tube is intended to be used to internally shunt blood vessel during anastomosis constructions. The shunt allows blood to be delivered distally past the anastomosis site preventing ischemia while the target coronary artery is opened and surgical grafted to a donor vessel. The bypass shunt is to be removed prior to the final sutures being performed. Select the blood vessel bypass tube which is appropriate for the internal diameter of the blood vessel.

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032977